





**Application No.: 09/965,738**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Is/are the Application of:**

O'BRIEN, ET AL.

Serial No.: 09/965,738

Filed: September 27, 2001

For: REPEAT SEQUENCES OF THE CA125  
GENE AND THEIR USE FOR DIAGNOSTIC  
AND THERAPEUTIC INTERVENTIONS

) Attorney Docket No.: 022438.43867

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop: DD  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-A820. A copy of each of the references listed on the attached form is submitted herewith.

Applicants respectfully request that the Examiner consider each listed document and indicate that it was considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute “prior art”. If the Examiner applies the document as prior art against any claim in the application and Applicants determine that the cited documents do not constitute “prior art” under United States law. Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

**Document AA** - International Publication No.: WO 00/36107 (published June 22, 2000) by Corixa Corporation discloses compositions and methods for the therapy and diagnosis of cancer, such as ovarian cancer. Compositions may comprise one or more ovarian carcinoma proteins, immunogenic portions thereof, polynucleotides that encode such portions or antibodies or immune system cells specific for such proteins. Such compositions may be used, for example, for the prevention and treatment of diseases such as ovarian cancer. Methods are further provided for identifying tumor antigens that are secreted from ovarian carcinomas and/or other tumors. Polypeptides and polynucleotides as provided herein may further be used for the diagnosis and monitoring of ovarian cancer.

**Document BB** - European Patent Application No.: 0 288 082 (published October 26, 1988) by O'Brien discloses a 40 kilodalton subunit of CA125 antigen, useful in the diagnosis and monitoring of ovarian cancer. It also relates to an immunoassay method for detection of the antigen in serum for diagnosis and monitoring purposes.

**Document CC** - International Publication No.: WO 02/092836 (published November 21, 2002) by Lloyd, et al. disclose an isolated nucleic acid molecule comprising sequences encoding the CA125 protein or a portion thereof. This invention also provides a method to detect ovarian cancer in a subject. Furthermore, this invention provides a method for the diagnosis of a cancer which expresses CA125 by detecting CA125-expressing cells in the blood or other fluids of patients. This invention also provides a method of producing CA125 protein. Finally, this invention provides a method to treat or prevent cancer using a vaccine comprising CA125 nucleic acid or protein.

**Document DD** - "More than 15 years of CA125: What is known about the antigen, its structure and its function" T.J. O'Brien, et al. *The International Journal of Biological Markers*, Vol. 13, no. 4, pp. 188-195.

**Document EE** - "Isolation and Characterization of Ovarian Cancer Antigen CA125 Using a New Monoclonal Antibody (VK-8): Identification as a Mucin-type Molecule" Kenneth O. Lloyd, et al. *Int. J. Cancer*: 71, 842-850 (1997).

**Document FF** – "Immunohistochemical Characterization of 22 Monoclonal Antibodies against the CA125 Antigen: 2nd Report from the ISOBM TD-1 Workshop" M. Nap, et al. *Tumor Biol.* 1996; 17: 325-331.

**Document GG** – "Human Mucin Gene MUC5B, the 10.7-kb Large Central Exon Encodes Various Alternate Subdomains Resulting in a Super-repeat" Jean-Luc Desseyn, et al. *The Journal of Biological Chemistry*, Vol. 272, No. 6, Issue of February 7, pp. 3168-3178, 1997.

**Document HH** – "Isolation of the Murine Nbrl Gene Adjacent to the Murine Brcal Gene" Julie Chambers, et al. *Genomics* 38, 305-313 (1996).

**Document II** – <http://www.ncbi.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=2566012>. "Nucleotide" Lee Helman, M.D., et al. NCBI Sequence Viewer.

**Document JJ** – "Molecular Cloning of the CA125 Ovarian Cancer Antigen" Beatrice W.T. Yin, et al. *The Journal of Biological Chemistry*, Vol. 276, No. 29, Issue of July 20, pp. 27371-27375, 2001.

**Document KK** - "The CA125 Gene: An Extracellular Superstructure Dominated by Repeat Sequences" Timothy J. O'Brien, et al. *Tumor Biol* 2001;22:348-366.

**Document LL** - "The CA125 Gene: A Newly Discovered Extension of the Glycosylated N-Terminal Domain Doubles the Size of This Extracellular Superstructure" Timothy J. O'Brien, et al. *Tumor Biol* 2002;23:154-169.

In the event the Examiner has any questions regarding this document, please contact the undersigned at the telephone number listed below.

Respectfully Submitted,

Butler, Snow, O'Mara, Stevens &  
Cannada, PLLC

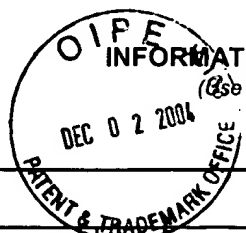
11-30-04  
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, on 11-30-04 in an envelope addressed to: Mail Stop: DD, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Lori L. Wood  
Lori L. Wood



ATTY DOCKET NO. <b>022438.43867</b>	APPLICATION NO. <b>09/965.738</b>
APPLICANT(S) <b>O'Brien, et al.</b>	
FILING DATE <b>September 27, 2001</b>	GROUP ART UNIT

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

**U.S. PATENT APPLICATION PUBLICATIONS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

**FOREIGN PATENT DOCUMENTS**

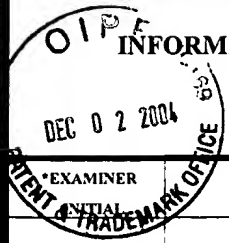
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AA	WO 00/36107	06/22/00	World	C12N 15/12	C07K 14/47	✓	
	BB	0 288 082	10/26/88	Europe	C07K 15/14	C12P 21/00	✓	
	CC	WO 02/092836	11/21/02	World	C12Q		✓	

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

	DD	"More than 15 years of CA125: What is known about the antigen, its structure and its function" T.J. O'Brien, et al. The International Journal of Biological Markers, Vol. 13, no. 4, pp. 188-195
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EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

 <p><b>OIPF INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)</p>		Docket Number (Optional) <b>022438.43867</b>	Application Number <b>09/965,738</b>
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